PTO-1390 (Rev. 07-2005) (\$)

Approved for use through 3/31/2007, OMB 0651-0021

Approv

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

INTERNATIONAL APPLICATION NO.

ATTORNEY'S DOCKET NUMBER RO4126US (#90568)

PRIORITY DATE CLAIMED

U.S. APPLICATION e CFR 1.5)

PCT/EP2004/006659 19 June 2004 (19.06.2004) 27 June 2003 (27.06.2003)					
TITLE OF INVENTION Transmucosal Form of Administration with Reduced Mucosal Irritation					
APPLICANT(S) FOR DO/EO/US RADEMACHER, Tina and VON FALKENHAUSEN, Christian					
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:					
This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.					
This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.					
This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.					
4. X The US has been elected (Article 31).					
5. X A copy of the International Application as filed (35 U.S.C. 371(c)(2))					
a. $\overline{\mathbf{X}}$ is attached hereto (required only if not communicated by the International Bureau).					
b. has been communicated by the International Bureau.					
c. is not required, as the application was filed in the United States Receiving Office (RO/US).					
6. X An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).					
a. $\overline{\mathbf{X}}$ is attached hereto.					
b. has been previously submitted under 35 U.S.C. 154(d)(4).					
7. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))					
a. are attached hereto (required only if not communicated by the International Bureau).					
b. have been communicated by the International Bureau.					
c. have not been made; however, the time limit for making such amendments has NOT expired.					
d. X have not been made and will not be made.					
8. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).					
9. X An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).					
10. X An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).					
Items 11 to 20 below concern document(s) or information included:					
11. X An Information Disclosure Statement under 37 CFR 1.97 and 1.98.					
An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.					
A preliminary amendment.					
14. X An Application Data Sheet under 37 CFR 1.76.					
15. X A substitute specification.					
16. X A power of attorney and/or change of address letter. (Power of Attorney included w/Declaration - #9 above)					
17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.					
18. A second copy of the published International Application under 35 U.S.C. 154(d)(4).					
A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).					

INTERNATIONAL FILING DATE

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. Page 1 of 3

IAP9 Rec'd PCT/PTO 27 DEC 2009

PTO-1390 (Rev. 07-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION	J.S. APPLICATION NO. (if known, see 37 CER 15) 10/562422 INTERNATIONAL APPLICATION PCT/EP2004/006659			RO4126US (#90568)		
20. Other items or information: Publication No. WO 2005/000263 (first page only); PCT/ISA/210; Written Opinion; Response to Written Opinion; IPER with annexes; return postcard receipt						
The following	g fees have b	een submitted			CALCULATIONS	PTO USE ONLY
21. X Basic national fee (37 CFR 1.492(a))			\$ 300.00			
22. X Examination fee (37 CFR 1.492(c))						
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)					\$ 200.00	
23. X Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)\$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority					\$ 400.00	
TOTAL OF 21, 22 and 23 =			900.00			
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.						
Total Sheets Ex	tra Sheets	Sheets Number of each additional 50 or fraction thereof (round up to a whole number)				
17 - 100 =	17 ₋₁₀₀ = -83 /50 = x \$250		\$ 0.00			
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).					\$ 0.00	
CLAIMS	NUMB	ER FILED	NUMBER EXTRA	RATE	\$	
Total claims	32	- 20 =	12	x \$50	\$ 600.00	
Independent claims	3	- 3 =	0	x \$200	\$ 0.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360				\$ 0.00		
TOTAL OF ABOVE CALCULATIONS =				\$ 1,500.00	Y .	
Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.				0.00		
SUBTOTAL =				\$ 1,500.00		
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	0.00	
TOTAL NATIONAL FEE =				\$	1,500.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +					\$	40.00
TOTAL FEES ENCLOSED =					\$	1,540.00
					Amount to be refunded:	\$
					Amount to be charged	\$

10/562422

Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

	IAPS ROC O PCT/PTO 27 DEC 2009					
a. A check in the amount of \$	to cover the above fees is enclosed.					
b. Please charge my Deposit Account No	in the amount of \$ to cover the above fees.					
c. X The Commissioner is hereby authorized to charge any Account No. 08-2441 . A duplicate copy of this st	additional fees which may be required, or credit any overpayment to Deposit neet is enclosed.					
d. Tees are to be charged to a credit card. WARNING: In be included on this form. Provide credit card information	nformation on this form may become public. Credit card information should not attended attended attended attended at the company of the compa					
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed						
and granted to restore the International Application to pend	aing status.					
SEND ALL CORRESPONDENCE TO: D. Peter Hochberg	SearMelling					
D. Peter Hochberg Co., L.P.A.	SIGNATURE Sean Mellino					
1940 East 6th St 6th Floor	NAME					
Cleveland, OH 44114	48,817					
US	REGISTRATION NUMBER					
	•					
· ·						

EXPRESS MAIL CERTIFICATION UNDER 37 CFR 1.10

"Express Mail" label number: EV713319914US

Date of deposit

December 27, 2005

I hereby certify that the paper(s) identified above, and any document(s) referred to as attached hereto, is being deposited with the United States Postal Service on the date indicated in an envelope as "Express Mail Post Office to Addressee" and is addressed: Mail Stop PCT,

Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia, 22313-1450.

Christine Kolnon

Christine Kotran